

REMARKS

Claims 1-7 and 9-15 are pending. Claims 1, 2, 5 and 13 are amended to more fully describe the invention and Claim 8 is canceled.

Amendments to the Claims

Support for the amendments can be found throughout the specification, in particular reference to a subject in need thereof as recited in amended Claims 1 and 2 is supported at least on page 16, lines 2-7. In addition, Claim 5 is amended into independent form by incorporating recitations from Claim 1. No new matter has been added.

Double Patenting Rejection

Claims 1, 3-4, 6, 9 and 11-12 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,319,893 (the '893 patent). Applicants, respectfully traverse this rejection and request reconsideration and withdrawal of the rejection because a method of treating anxiety as recited in the instant claims is not an obvious variant of a method of raising the blood sugar level as recited in the '893 patent.

The U.S.P.T.O. states that the '893 patent discloses treatment of low blood sugar by administration of inhibitors of DP IV and that one skilled in the art readily appreciates the close relationship between interdependent physiological processes such as hypoglycemia, stress and anxiety. Therefore, it is concluded that because the '893 patent discloses treatment of low blood sugar by administration of inhibitors of DP IV, anxiety syndrome associated with low blood sugar is inherently treated. The U.S.P.T.O. cites U.S. Patent No. 4,024,250 (the '250 patent) and, in an earlier office action, Lader (*J. Clin. Psychopharmacology* 1: 342-349, 1981) in support of the art recognition of a relationship between hypoglycemia and anxiety. It is noted, however, that the '893 patent itself provides no disclosure whatsoever of the treatment of anxiety. Further, the '250 patent references anxiety as related to hypoglycemia in patients in which the body's regulatory systems are defective (Column 2, lines 18-30) or in chronic hypoglycemia (Column 2, lines 53-68). In addition, the earlier citation by the U.S.P.T.O. of Lader references idiopathic hypoglycemia as having features in common with anxiety (see abstract). Such references are to specific types of hypoglycemia, but hypoglycemia is not consistently or inherently associated with anxiety. "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Cont'l Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1269, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991).

Furthermore, inherency is not the correct test for obviousness-type double patenting. Instead, the correct test is whether the claimed invention is merely an obvious variant of what has been patented. *Georgia-Pacific Corp. v. United States Gypsum Co.*, 52 USPQ2d 1590, 1593 (Fed. Cir. 1999); *General Foods Corp. v. Studiengesellschaft Kohle mbH* 23 USPQ 2d 1839, 1843 (Fed. Cir. 1993).

Obviousness double patenting rejections are evaluated by an obviousness analysis as is performed for rejections under 35 U.S.C. § 103. *In re Longi et al.* (CA FC) 225 USPQ 645 648 n. 4 (Fed. Cir. 1985) (a double patenting of the obviousness type rejection is "analogous to [a failure to meet] the non-obviousness requirement of 35 U.S.C. §103, except that the patent principally underlying the double patenting rejection is not considered prior art"). Further, in an evaluation of the patentability of method claims, recitations of "a method of treating a disease" and "to a patient in need thereof" are construed as claim limitations that distinguish the application claims over prior disclosures of methods of treating different diseases. For example, the Federal Circuit has held that a prior art disclosure of the treatment of anxiety in patients suffering from sleep apnea did not anticipate or render obvious claims to the treatment of sleep apnea. *Rapoport v. Dement*, 59 USPQ2d 1215, 1219-21 (Fed. Cir. 2001)("The FPR Publication was limited to treatment of anxiety in patients suffering from sleep apnea" and "[t]here is no disclosure in the FPR Publication of tests in which buspirone is administered to patients suffering from sleep apnea with the *intent to cure the underlying condition*" (emphasis added)). See also *Jansen v. Rexall Sundown Inc.* 68 USPQ2d 1154, 1158 (Fed. Cir. 2003)(The preamble "is a statement of the intentional purpose for which the method must be performed" and "administering the claimed vitamins in the claimed doses for some purpose other than treating or preventing macrocytic-megaloblastic anemia is not practicing the claimed method, because Jansen limited his claims to treatment or prevention of that particular condition in those who need such treatment or prevention.").

Thus, "[a] method of treating anxiety" in "a subject in need thereof" as recited in Claim 1 is a limitation of the claim. Further, such purposeful treatment of anxiety is an intent to treat the underlying condition of anxiety and it is not an intent to raise the blood sugar level. "A method of treating anxiety" is, therefore, very different from and not an obvious variant of "[a] method of raising the blood sugar level" as recited in Claims 1-4 of the '893 patent. Consequently, Claims 1, 3-4, 6, 9 and 11-12 do not constitute obviousness-type double patenting with respect to Claims 1-4 of the '893 patent and reconsideration and withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. § 112, 2nd paragraph

Claim 2 and Claims 7, 10 and 14 by dependency stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite because of omission of the recitation of intended goal of the method after the words "for the treatment of." Reconsideration of the rejection is requested in view of the amendment of Claim 2 which now recites "for the treatment of anxiety." It is believed that this amendment of Claim 2 obviates the rejection and withdrawal of the rejection is respectfully requested.

Objections to Claims

Claims 5, 13 and 15 were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all limitations of the base claim and any intervening claims. Accordingly, Claim 5 is rewritten in independent form to include the recitations of Claim 1 from which Claim 5 had depended. It is believed that this amendment obviates the objection and reconsideration and allowance of the claims is respectfully requested.

CONCLUSION

For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the rejections and objections of the claims. It is believed that the claims as currently presented are in a condition for allowance and such favorable action is respectfully requested. If any questions arise or if any issues remain to be resolved, it is requested that the U.S.P.T.O contact the undersigned attorney.

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